



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1997

William F. Zingheim, DDS
Opti-Max Corporation
6281 Oak Bay Road
Port Ludlow, Washington 98365

Re: K972769
Trade Name: Opti-Max Angled Crown Post for Externally-
Hexed Implants
Regulatory Class: III
Product Code: DZE
Dated: July 11, 1997
Received: July 24, 1997

Dear Dr. Zingheim:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

To: Renita Hoard

Page 1 of 1

510(k) Number (if known): K 97 - 2769

Device Name: Opti Max ANGLED CROWN POST for

Indications For Use: Externally - Hexed Implants

The Opti-Max angled crown post for externally-hexed implants is intended to be used as an abutment for a cast crown, to be retained by cementation. The metal for this cast crown is to be composed of a compatible formulation when in contact with Ti6Al4V. If light retention is desired by the clinician zinc-oxide cement can be used, if stronger retention is desired, carboxylate cements may be used. The cast crown seated on this crown post may be single and free-standing, part of fixed bridgework, or connected to a bar structure for overdenture retention.

For additional information, please see page 11 - Indications for use

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K0727109

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use